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Configuration Management Program Description

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Configuration Management Program Description•

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Configuration Management Program Description

1.0 Introduction

Configuration management (CM) is a quality assurance (QA) support function that, in conjunction with the Integrated Safety Management System (ISMS), is used to help the Laboratory achieve its safety goals. The CM and QA Programs provide a systematic process for assuring the status of facility safety basis requirements, and maintaining the appropriate descriptive documentation. The CM Program implements a graded approach, applying greatest rigor to management of configuration items (CIs) whose failure poses the greatest risks. See Appendix A for the definitions of CM-related terms.

CM requirements are specified in the Work Smart Standards (WSSs), which are part of the Laboratory's contract with the Department of Energy (DOE). The elements of CM are consistent with and contained in the Laboratory's *Configuration Management Standard* (UCRL-AR-133351 Rev. 1), Document 3.1, "Safety Analysis Program," and Document 41.1, "LLNL Quality Assurance Program," in the *Environment, Safety, and Health (ES&H) Manual*. The implementation of other programs (e.g., the QA and Safety Analysis Programs) that satisfy portions of this document may be referenced in CM Plans.

1.1 Purpose and Objectives

The purpose of the CM Program is to establish the CM mechanisms for consistency between the appropriate design requirements, physical configuration, and documentation of CIs necessary to protect workers and the public during the lifecycle of a facility. This document describes the institutional program (i.e., the CM Program) that satisfies the CM-related WSSs (Section 9.0) and defines the requirements for implementation of the CM Program at the directorate and facility levels.

1.2 Scope

This document applies to all facilities, specifically to structures, systems, and components (SSCs) and operations required to maintain the facility safety basis. An appropriately tailored CM Program can benefit work processes, as well as safety. The CM Program is to be implemented on a "go forward" basis unless a significant safety issue is determined to exist in the "as found" configuration. Directorates may also use this document to develop and implement an integrated CM Program for items not required by their safety analyses. Specific strategies for implementing the "go-forward" approach for CIs shall be discussed in directorate-level CM Plans (DCMPs), facility CM plans, or other CM-related documents referenced in the DCMPs.

1.3 Configuration Management Elements

CM requirements set forth in the Laboratory WSS *Configuration Management Standard* consist of five elements:

1. Program management (see Section 2.0)
2. Design requirements (see Section 3.0)
3. Document control (see Section 4.0)
4. Change control (see Section 5.0)
5. Assessments (see Section 6.0)

1.4 Plan and Schedule

For information about specific implementation schedules, contact a directorate assurance manager or the CM subject-matter expert (SME).

2.0 Program Management

This section describes LLNL CM Program management processes. The objective of the program management element is to direct and monitor the development and implementation of the overall CM Program. The purpose of CM Program management is to provide processes that define program objectives and identify the actions and tasks for accomplishing and managing those objectives. Other typical program management functions may include estimating the level of effort needed to complete each task, organizing and scheduling the planned tasks, staffing an organization to accomplish the planned tasks, assigning personnel to specific tasks, monitoring progress during the implementation, identifying problems and taking corrective actions, and recognizing tasks and program completion.

2.1 Overview

Each directorate shall document its Directorate CM Program in a directorate plan(s) (i.e., a DCMP) that, when implemented, addresses the requirements in this document. The DCMPs are directorate documents encompassing CM guidelines and requirements for appropriate directorate's facilities. In addition, facility CM documents or plans may be utilized as appropriate to implement the DCMPs at the facility level. In both cases, See Appendix B for a generic directorate document hierarchy chart. When utilized, the facility level documents or plans shall define CM roles and responsibilities of the participating organizations. The DCMPs shall identify the hierarchy of CM documents (which contain specific CM requirements and guidelines).

2.2 Configuration Management Activities

The required activities associated with CM are:

- Developing the DCMPs, facility CM plans, or other CM documents.
- Determining the CIs based on facility safety basis documents.
- Determining the configuration level and the owner of each CI.
- Identifying the controlling documents for each CI.
- Controlling changes to the CIs.
- Evaluating the effectiveness of the implementation of the Directorate CM Program.

CM activities are conducted by the directorates for their facilities and administered in accordance with the DCMP. Directorates may elect to group multiple facilities under one or several CM Plans.

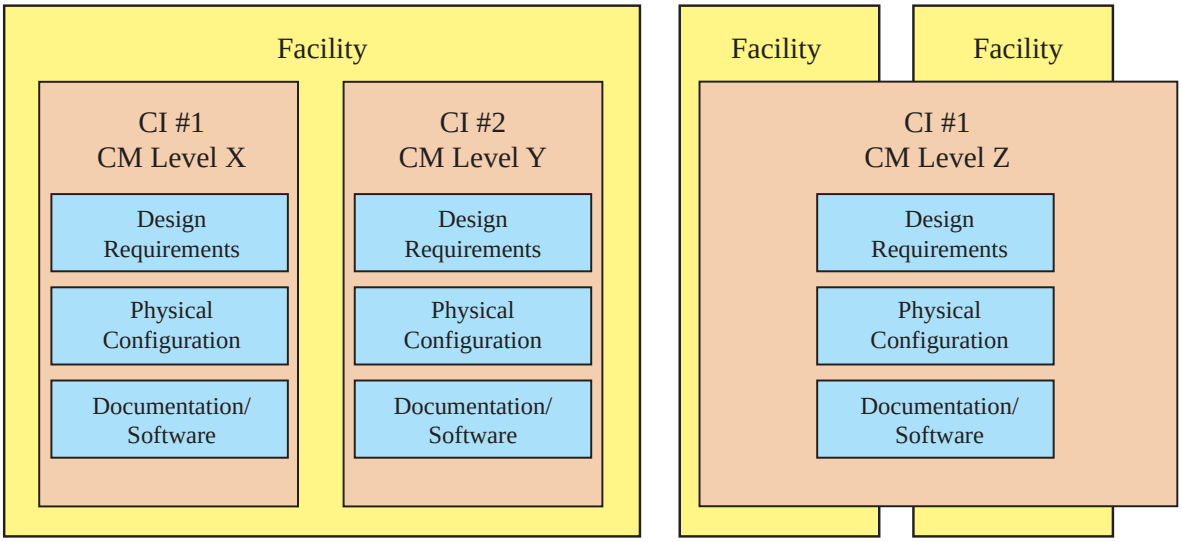
2.3 Configuration Items

The basic unit of CM is the CI, which typically comprises the facility safety system, structure and component (SSC), that are part of the safety basis, and the associated design requirements, physical configuration, documentation, and software (see Figure 1). CIs apply to the facilities for which the directorate has operational responsibility or institutional functions that cross directorate boundaries and support safety basis commitments. CIs are derived from the analyses in safety basis documents.

Directorate and facility management shall assign CI owners (who may be system engineers) as appropriate within their areas of responsibility and shall coordinate the definition of CIs that span multiple directorates.

CI owners shall identify, and ensure the maintenance of, the documents, records, and software for each CI. As a whole, this aggregate constitutes and defines a CI.

Directorates may choose to align CIs within facility boundaries (see Figure 1.a). Directorates may choose to manage multiple CIs within one facility—especially when the facility contains a mixture of hazards. Directorates with institution-wide responsibility may choose to group Laboratory-wide SSCs under one CI. Some CIs may cross one or more facility boundaries (see Figure 1.b).



1.1.a — CIs within facility boundaries **1.1.b — CI crossing facility boundarie**

Figure 1. Configuration item examples.

2.4 Implementation

Following DCMP approval by the AD, CM implementation shall address all five elements of the CM Program. The process for implementing the CM Program shall be accomplished in the following steps:

1. Identify the boundary of each CI.
2. Determine the configuration level and CI owner for each CI.
3. Identify the existing baseline status for CIs.
4. Identify organization interfaces (e.g., between facility owners and programs) in directorate-owned facilities and, where appropriate, establish the interfaces in writing. Under a CM plan that crosses organizational lines, for example, organizations such as the Plant Engineering, Hazards Control, and Procurement and Materiel Departments and the Hazardous Waste Management Division can become validated providers of key CM elements to multiple directorates.

2.5 Description and Identification of Configuration Items

For each facility or group of facilities, each directorate shall review safety basis documents to identify and categorize each CI. Safety analysts should be involved in this review. The following information should be documented or referenced in the appropriate CM documents:

1. Title or name of CI.

2. CI owner.
3. CM Level.
4. Brief description of CI.
5. Required documents, records, and software components of the CI (e.g., safety basis documents, specifications, design documents, design criteria, performance criteria, formal basis of design documents, operations and maintenance manuals, lists, and software data).
6. The functional organizational structure of those involved in the CM process.

3.0 Design Requirements

The objective of the design requirements element is to establish and maintain the design requirements and the associated design basis. Design requirements consist of documentation such as specifications and drawings and shall be formally established, documented, and maintained. CI design requirements are dynamicin that CIs and CI documents can be added or deleted throughout the facility's lifecycle. Documents are added, changed, or deleted using the change control process (see Section 5.0), which ensures the current configurations are known and controlled at all times.

3.1 Establishing Design Requirements

Establishing CI design requirements begins with the identification and categorization of a facility's CIs, which are derived from the safety basis documents [e.g., Safety Analysis Reports (SARs), Safety Assessment Documents (SADs), Bases for Interim Operation (BIOs), HARs, and SCRs]. Each CI shall have a designated CI owner.

CI boundaries shall be well defined so that interfaces with other systems are clearly identified. Identifying interfaces is important both for clearly identifying the scope of the CI and for interfacing systems that may have different CM levels or CM owners. For CIs to meet the safety requirements specified in the safety basis documents, directorates shall maintain identification of the specific requirements documents. The graded approach shall be used to categorize and implement CM for each CI, using the CM levels identified in Table 1.

3.2 Identifying the Design Document Set

Each CI shall have a designated set of documents that define the CI's design requirements and its corresponding design bases. Section 4.1 provides information on document types that need to be controlled under the LLNL CM Program. The CI owner is responsible for determining the specific documents that make up the design requirements for the CI.

Table 1. Configuration management levels for LLNL facilities.

Hazard category	Hazard analysis mechanism[a]	Control document	CM Levels[b]		
			CM Level 3	CM Level 2	CM Level 1
General industry	SCR	SCR, ES&H Manual	RSS		
Low hazard	HAR	HAR, FSP	RSS		
Radiological (< Cat. 3 Nuclear)	HAR	HAR, FSP	RSS		
Accelerator	SAD	SAD, FSP, ASE	RSS		
Moderate hazard	SAR	SAR, OSR, FSP	RSS	RSS	
Explosive	SAR	SAR, OSR, FSP	RSS	RSS	
Cat. 3 Nuclear	SAR, DSA	SAR, TSR, DSA, FSP	RSS	SS-SSC	
Cat. 2 Nuclear	SAR, DSA	SAR, DSA, TSR, FSP	RSS	SS-SSC	SC-SSC

[a] CI change control documents are identified in Document 3.1 in the *ES&H Manual.*

[b] Levels depicted are typical. Section 7.1 should be used to determine the final CM level.

3.3 Determining the Adequacy of Design Requirements

An appropriate level of technical management review should be held to validate and document the set of design requirements that are to be maintained for each CI. Where design requirements are identified by safety basis analyses, but which are not going to be controlled as CIs, the reason for the decision should be documented. An initial assessment is one mechanism that can be used during implementation of CM to determine the adequacy of design requirements; others include operational experience, maintenance and operational tests, and surveillance tests. Technical management review shall be incorporated into the CM Program.

4.0 Document Control

The objective of the document control element is to identify and maintain documents to be controlled within the CM Program and to keep those documents consistent with the physical configuration and design requirements. The hierarchy of CM documents, in descending order, includes the LLNL CM Standard; this document; DCMPs; directorate level procedures (if any); and facility CM plans, procedures, or other implementing instructions (See Appendix B). Document control in CM involves the following functions, which shall be consistent with the directorate's QA Plans:

- Identifying the types and specific documents to be included within the CM Program.
- Storing identified documents.

- Controlling and tracking documents within the CM Program.
- Retrieving documents within the CM Program in a timely manner.

Review and approval of document changes and revisions are addressed in Section 5.0.

4.1 Identification of Documents

It is the responsibility of the CI owner, working with supporting organizations, to identify and list the required documents or document sets for a CI. The document owner is the functional organization or individual responsible for developing and revising the technical content of the document.

Changes to the design and operation of SSCs may require changes to other documents, so the CI owner must be aware of the other documents, e.g., facility safety basis documents, site safety documents, Facility Safety Plans (FSPs), and Operational Safety Plans (OSPs).

4.2 Storage of Documents and Records

This section discusses requirements for document and record storage, which shall be compatible with the various directorate- and activity-level QA Plans and procedures.

4.2.1 Methods of Storage

Record copy documents shall be stored in a manner that is appropriate for the particular characteristics of the document media and that prevents damage or loss from deterioration, common mode failures, or obsolescence of technology. Special media characteristics (e.g., sensitivity to light, pressure, magnetic fields, and temperature) should also be considered. Copies of the items that are records may be distributed from the secure storage locations. Other storage considerations (e.g., those imposed by classification and security) should also be taken into account, if appropriate.

4.2.2 Retention Times

For all CM levels, record retention times shall be established to meet the needs of facility or program management and to meet currently established retention schedules, which are available at the following Internet address:

https://www-ais.llnl.gov/llnl_only/docs/bsd/records/retention/retention.html

4.2.3 Accessibility and Retrievability

Defined maximum retrieval times and processes should be established to ensure documents and records are available when needed for the purpose required. Documents that reflect the facility's design or that are necessary for day-to-day operation may have shorter required retrieval times. Documents and records shall be accessible to the document or record owners and to the facility management and the CI owner (if different from the document owners). Special procedures and controls may be necessary to meet the needs of both parties.

4.3 Control and Tracking

Document control features are primarily intended to assure that only the currently approved revisions of documents within the CM Program are in use and that appropriate historical information is maintained. Tracking features support this aim by maintaining current status documents and pending changes. Records control features are intended to assure that appropriate historical information is maintained.

4.3.1 Procedures

Directorates and programs shall develop procedures necessary to assure that document control, storage, and retrieval requirements and methods are clearly established. The roles and responsibilities of key document control personnel shall be established. Because of the potentially large number of interface and procedure requirements between facilities and support organizations, such crosscutting (i.e., cross-organizational) procedures should be consistent.

4.3.2 Distribution of Documents

Using a graded approach by CM level, a controlled document distribution list (when applicable) shall be established and maintained to identify the controlled documents and holders of up-to-date copies. Copies of new or revised documents shall be distributed to affected parties and (if applicable) in accordance with a controlled document distribution list. For CM Level 1 documents (i.e., documents involving controls for the most significant hazards), acknowledgement of receipt is appropriate. Recipients should follow procedures for updating their copy of the document. Such procedures may include discarding any obsolete pages or copies of documents, or returning the obsolete documents to the document controller.

A document database (or a list) of current controlled documents and records shall be developed, maintained, and made available by the document owner. The database list should contain, for each document, basic information that allows potential users to determine whether documents are current. For example, basic information should

include the document number, document title, document owner, current revision number or date, and current document status (e.g., requires revision, in revision, or issued).

5.0 Change Control

The objective of the change control element is to maintain consistency among the design requirements, physical configuration, and facility documentation as changes are made. This objective can be met if:

- Needed changes to a CI are properly identified, evaluated for impact to safety and to other components of the CI, executed in a controlled manner, and verified when complete.
- Any procedures, documents, and instructions that need to be updated as a result of the change are made current.
- Affected parties are made aware of the change.

5.1 Identification of Changes

Changes may include changes to hardware, maintenance procedures, processes, operations, documents, computer software, and inventory limits, as well as temporary modifications.

At the heart of an effective CM program is the currency and accuracy of the physical configuration of relied upon SSCs[1] and the safety basis documents. It is critical that the CI owner identify all connected or impacted systems when evaluating a change. Changes to a CI design or operation may require changes to other safety envelope documents, e.g., facility safety basis documents, site safety documents, emergency preparedness and response documents, FSPs, and OSPs.

It is important to differentiate between actual changes (i.e., modifications and alterations) and maintenance work that does not affect the configuration but does require monitoring, control, and status accounting. All changes other than "as is" replacements are changes, and temporary modifications should be considered for inclusion in some CM programs to assure the safety evaluation of changes and to provide interim documentation. The basic relationship between design requirements, documentation, and physical configuration should not change as a result of maintenance work, whereas modification work entails configuration changes.

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[1] An identified SSC (other than safety-class and safety-significant SSCs) relied upon to maintain a facility's safety basis.

5.2 Technical Review of Changes

Each specific proposed change shall be reviewed to determine whether it is within the bounds of the design requirements. If not controlled, operational activities could result in unintended and undocumented changes to CIs. Changing equipment set points for operator convenience, lifting leads, using mechanical or electrical jumpers, pulling circuit cards, disabling enunciator alarms, and making computer software changes are all examples of operational activities that could have secondary effects on the original configuration. Such operational activities shall be evaluated before implementation to ensure that the activities do not go undocumented, deviate from the established design requirements, or have a negative safety impact.

Post-installation testing shall be evaluated and (as appropriate) performed consistent with Table 2 each time a CI is modified. A new CI may require a system test to assure proper integration with other systems. Initial installation testing may be accomplished by QA acceptance testing.

5.3 Management Review of Changes

Before implementation of a proposed change, and as part of the change control process, management and the CI owner should review the change (even if it is not a change to design requirements) to verify that the technical reviews have been performed adequately, that the change package is complete and ready for implementation, and that any necessary external approvals have been obtained prior to implementation.

5.4 Change Control Flow and the Graded Approach

The flowchart in Figure 2 illustrates the typical flow of the change control element under this CM Program, and Table 2 gives the graded approach for implementing change control. The graded approach specified in Table 2 does not supercede the change control requirements specified in regulations or LLNL's contract with DOE.

6.0 Assessments

The objective of the assessment (self-assessment) element is to help define facility CM needs and to measure how effective the CM Program is in establishing and maintaining a program's basic relationships. CM assessments are to be conducted periodically throughout the life of the facility. Senior management of the organization responsible for a CI shall retain responsibility for the conduct of CM assessments and for assuring that corrective actions are taken for deficiencies noted in the assessments. Applicable external assessments that are conducted as part of LLNL QA processes are acceptable for fulfilling the CM assessment requirements.

Table 2. Graded approach for the change control process.[a]

Action	CM Level 3	CM Level 2	CM Level 1
Initiate change request	Change review document		
Evaluate impact and alternatives	Using applicable evaluation documents CI owner	Using applicable evaluation documents CI owner and facility management	Using applicable evaluation documents CI owner, facility management, and SME
Prepare design change package	Applicable memo, Integration Work Sheet (IWS), drawings	Applicable memo, IWS, drawings, supporting analysis and calculations	Applicable performance specifications, analysis, calculations, drawings, and acceptance criteria calculations
Perform review of design change package	CI owner and facility management	CI owner and facility management	Design review team minimum: CI owner, facility management, and SME
Issue approval to implement change	Appropriate management		
Issue change documents	Distribute to affected parties	Controlled distribution to affected parties	Controlled distribution (with return receipt) to affected parties
Install change	Work authorization process per *ES&H Manual*, ISM, and work execution requirements		
Perform post-installation performance testing	Functional check with notification to facility management	Functional check with results notification to facility management	Acceptance criteria and acceptance testing with written notification to facility management
Revise CI operational documents	CI owner Review by user	CI owner Review by user and facility management	CI owner Review by user, facility management, designer, and SME
Issue release for operation after appropriate prestart review	Work authorization process per *ES&H Manual*, ISM, and work execution requirements		
Update remaining Documents	CI owner is responsible to ensure interfacing documents and systems are appropriately updated		
Close out change	Closeout of applicable change package		

[a] Refer to other *ES&H Manual* documents for specific revision and processing requirements for safety basis documentation (e.g., SARs, HARs, supporting calculations, FSPs, specific OSPs, SQRs, USIs, and USQs). For a given CM level, table entries are to be evaluated and followed if appropriate and if not in conflict with contract or regulatory requirements.

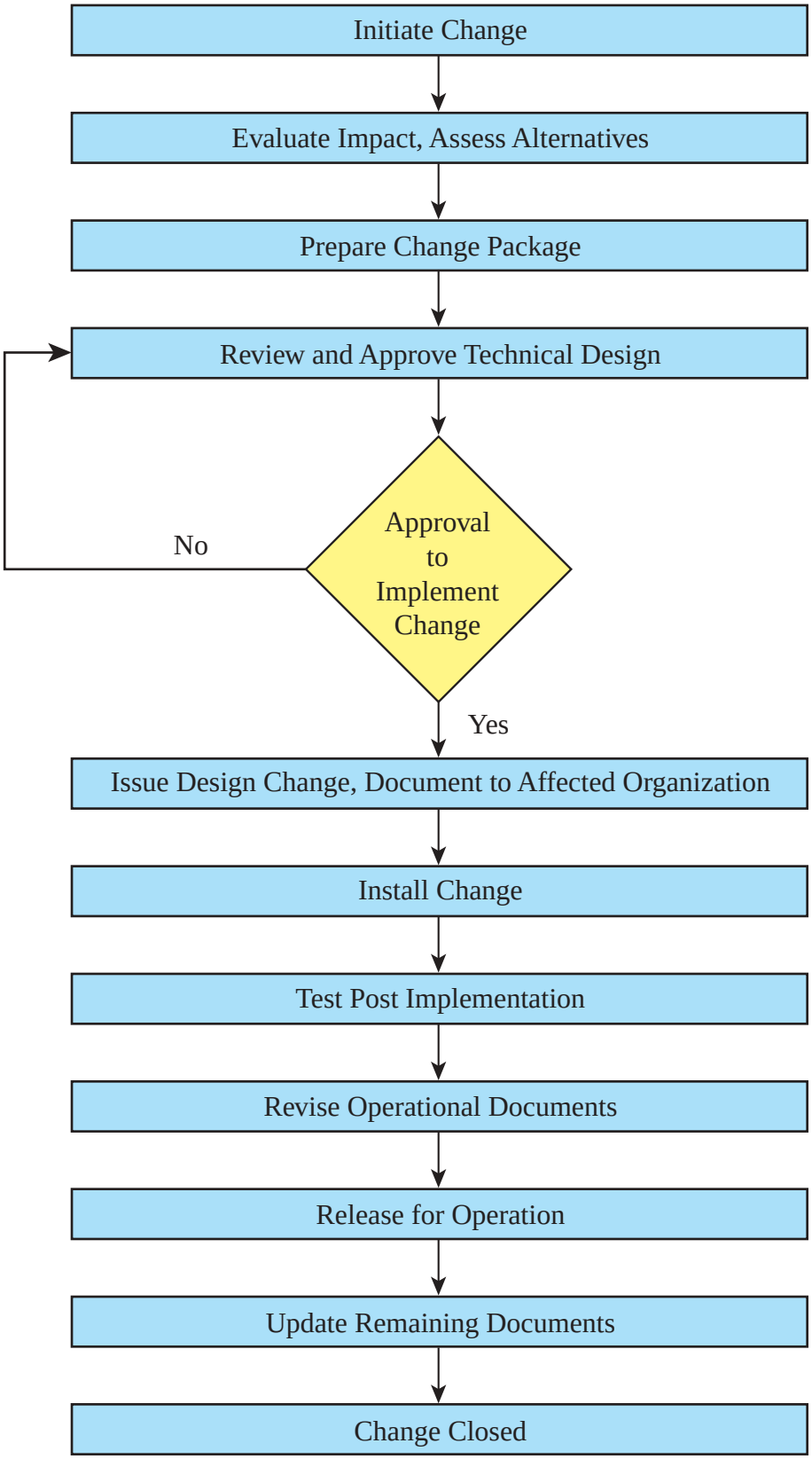

Figure 2. Change control flowchart.

6.1 Periodic Assessments

Each directorate shall provide for periodic management self-assessment of implementation of the CM Program according to the directorate's self-assessment plans. The directorates shall report the CM Program assessment results in their Annual Self-Assessment Reports. Self-assessments shall be conducted, using the graded approach, at a frequency and level of detail commensurate with the level of hazard present in facilities managed by the directorate. The results of self-assessments shall be documented and corrective actions for identified deficiencies developed and tracked in accordance with Document 4.1, "Directorate ES&H Self-Assessment Program," and Document 4.2, "ES&H Deficiency Tracking System," in the *ES&H Manual*.

6.2 Assessment Frequencies

A graded approach based on the CM level is to be applied to periodic CM self-assessments. The frequency of assessments should be a minimum of every three years. A statement of the frequency of the CM assessments shall be contained or referenced in the DCMP. Assessments are to evaluate the effectiveness of the CM Program on the basis of a representative sample of CIs. Assessments shall address periodic effectiveness of the five CM Program elements, including program management, design requirements, document control, change control, and assessments.

7.0 Graded Approach

This section specifies the concepts and examples for applying the graded approach to operational CM. For additional information, refer to Section 1.4 of DOE-STD-1073-93-Pt. 1, "Guide for Operational Configuration Management Program."

7.1 Configuration Management Levels

LLNL has established three CM levels, with CM Level 1 having the greatest amount of rigor and formality in its implementation, and CM Level 3 having the least amount of rigor and formality. The levels are defined as follows:

CM Level 1: Systems whose failure could result in impacts exceeding the offsite radiological evaluation guideline of 25 rem.

CM Level 2: Systems whose failure is estimated to result in acute worker fatality or serious injury to workers between the facility perimeter and the site perimeter.

CM Level 3: Systems whose failure is estimated to result in acute worker fatality or serious injury to workers within a facility perimeter.

As a result, a single facility may contain CIs of different CM levels, depending on the hazards associated with the CIs. The CM level of a CI is defined according to the significance of the hazard being controlled. To determine the CM level of an item using Table 1, do the following:

1) Evaluate safety basis documents and hazards-defining documents to determine the facility hazard categories, and select specific CIs accordingly [e.g., an emergency diesel generator (which is a CI) in a moderate hazard facility].

2) Compare the CI's characteristics with the definitions of the elements shown on the right side of Table 1, and decide the item's level of concern (e.g., an RSS concern that is outside the facility but still onsite).

3) Place the CI into the proper category defined under the three right-hand columns (e.g., CM Level 2).

Further guidance on the graded approach process is provided in Document 5.1, "Glossary of ES&H Terms," and Document 41.1, "LLNL Quality Assurance Program," in the *ES&H Manual*. In addition, 10 CFR 830.3 defines the graded approach, and 10 CFR 830.7 requires the use of the graded approach process "where appropriate." In addition, Chapters 1 and 2 of DOE-STD-1073-93 contain guidance on the development and implementation of an operational CM program. (DOE-STD-1073-93 is intended as guidance and therefore does not impose additional requirements.)

7.2 Grading Example

If, in the opinion of a directorate, the application of a CM Program to a system would have a detrimental effect on risk, then the directorate shall discuss their graded risk-based measures in a DCMP.

An example of a measure with a detrimental effect on risk would be the implementation of an unsafe DCMP CM Level 1 requirement to return obsolete, contaminated documents to the document owner after changes are made. If the subject documents are stored or used in a contaminated area, then the following compensatory action could be taken: Instead of monitoring and decontaminating the document for timely retrieval from the contaminated area, the obsolete document could be stamped OBSOLETE in red ink until disposal as contaminated waste. The revised document would then be the proper and identifiable document and could be properly utilized in the same potentially contaminated area.

8.0 Responsibilities

General responsibilities for all workers are described in Document 2.1, "Laboratory and ES&H Policies, General Worker Responsibilities, and Integrated Safety Management," in the *ES&H Manual*." Specific CM responsibilities for key personnel are listed under each title in the following sections.

The Laboratory CM Program shall be managed, directed, and monitored. LLNL has implemented ISM and QA programs to strengthen its ES&H management processes. Implementation is accomplished through Directorate ISM Plans, CM Plans, and QA programs. Roles, responsibilities, and authorities flow down from the *LLNL Integrated Safety Management System Description* (UCRL-AR-132791) to the Directorate ISM Descriptions and, ultimately, to QA plans and this document. ISM principles require that responsibilities and accountabilities be assigned and that the QA Program (including CM) be integrated into the organization's management structure. This document integrates DOE Order 414.1A and 10 CFR 830.122 with the LLNL ISMS. The following assignments of responsibility address QA and ISM principles. The duties and responsibilities for CM at the directorate level shall be specified in appropriate CM documents.

8.1 Laboratory Director

The Director has overall responsibility for the CM Program at LLNL, for guiding the Laboratory to programmatic success safely and securely, and for establishing the appropriate processes and systems to ensure compliance with the WSSs.

8.2 Deputy Director for Operations

The Deputy Director for Operations (DDO) is delegated the overall operational authority to implement the Laboratory's CM Program. The DDO may execute this authority through the Associate Director (AD) for the Safety, Security, and Environmental Protection (SSEP) directorate. The DDO or designee:

- Approves the Laboratory's CM Program.
- Resolves CM Program issues that affect multiple directorates.
- Serves as LLNL's primary interface with the DOE or University of California regarding CM.
- Provides, through the Assurance Review Office (ARO), independent evaluations of the Laboratory's CM Program and an assessment of the implementation by the directorates.

8.3 Assurance Review Office

The ARO shall provide independent periodic assessments of the effectiveness of the Laboratory's CM Program as defined in this document and the status of implementation within the directorates. Individuals knowledgeable in the field of CM shall conduct the assessments. It is recommended that independent assessments cover the five CM elements and the following over a triennial period: The physical configuration, document integrity, software integrity, and cross-directorate CM Program consistency. The results of the independent assessments shall be documented and reported to the DDO and SSEP AD.

8.4 Safety, Security, and Environmental Protection Associate Director

The CM subject-matter expert (SME) shall be designated by the SSEP Directorate AD as an individual who is technically competent in the CM subject-matter area.

The SSEP AD:

- Identifies and manages under CM, institutional documents, plans, and processes that cross directorate boundaries and are relied upon for maintenance of the site safety basis.

The CM SME:

- Reviews changes in CM standards and CM-related DOE orders and directives.
- Recommends and authors changes to the WSS set and the *ES&H Manual*.
- Advises the directorates on CM implementation issues.
- Provides for institutional CM training.

8.5 Associate Directors (AD)

Each AD is responsible for:

- Approving the DCMPs.
- Implementing the Laboratory's CM Program in his or her directorate.

8.6 Facility Management

Facility management, as described in the DCMP, shall:

- Adopt the DCMP to implement
  - — Facility-specific CM requirements, as necessary.
  - — A CM Program at the facility level (if necessary).

- Identify facility-specific CIs.
- Assign, or ensure the assignment of, a CI owner to all facility CIs.

8.7 Configuration Item Owner

The CI owner is responsible for identifying required documents (e.g., drawings, calculations, specifications, test criteria, applicable portions of documented hazard and accident analyses, and vendor manuals) that define the design requirements for a CI and ensuring system documentation is kept up to date. When a facility's design basis has not been clearly defined, the CI owner is responsible for identifying system requirements, performance criteria, and documents considered to be essential to system operation. The CI owner is responsible for maintaining the configuration of the CI.

9.0 Work Smart Standards

UCRL-AR-133351, Rev. 1, "Configuration Management Standard."

10.0 Resources for More Information

10.1 Contacts

See the ES&H Contact List.

10.2 Lessons Learned

For applicable lessons learned, refer to the following Internet address:

http://www-r.llnl.gov/es_and_h/lessons/lessons.shtml

10.3 Other Sources

10 CFR 830.122, "Quality assurance criteria."

DOE Good Practices Guide (GPG) FM–012, "Configuration and Data Management," Appendix E, "Document Control for Configuration Management" (April 1996).

DOE O 414.1A, "Quality Assurance," Attachment 1, "Contractor Requirements Document."

DOE-STD-1073-93-Pt. 1, "Guide for Operational Configuration Management Program," Sections 1.3 and 1.4 (November 1993).

DOE-STD-1073-93, Chapter 2, "Implementation Guidance for Operational Configuration Management."

Appendix A

Acronyms, Terms, and Definitions

Activity-Level Quality Assurance Plan	An activity- or facility-level document that details the implementation of QA within the activity or facility. An ALQAP is prepared when necessitated by unique sponsor requirements or the level of risk. The ALQAP may be combined with other activity- or facility-level documents.
ARO	Assurance Review Office.
As is	A disposition permitted for a nonconforming item when it has been established that the item is satisfactory for its intended use.
Change	Any alteration or addition, temporary or permanent, to the facility configuration, facility documentation, or design requirements. Changes not within current design requirements involve design changes. Identical replacements are not changes.
Change package	Work products of each step of the change process. The change package evolves during the change control process and forms the permanent record of the change.
Change review document	A document used to evaluate, implement, and document changes in facilities. (See Document 3.1 in the *ES&H Manual*.)
CI	See "Configuration item."
CM	See "Configuration management."
Configuration	The functional and physical characteristics of existing or planned hardware, firmware, software or a combination thereof as set forth in technical documentation and ultimately achieved in a product.
Configuration assessment	A formal examination to verify that a configuration item has achieved the performance and functional characteristics specified in its design documents.

Configuration item (CI)	Those SSCs from the safety basis whose performance parameters and physical characteristics are relied upon and need to be separately defined and controlled to provide management with the assurance needed to achieve the overall end-use function and performance.
Configuration management (CM)	An integrated management system designed to maintain integrity between design requirements, physical configurations (i.e., the facility and equipment in the facility), software, and associated documentation throughout the life of the facility.
Control document	A document that provides direction on what is important to safety and quality (ISQ). The control document may also provide directions on how to perform operations in a safe and quality manner. The directions come in the form of plans, rules, safety analyses, and requirements documents. Examples of these documents include the *ES&H Manual*, FSPs, DSAs, SARs, TSRs, OSRs, SADs, and ASEs.
DCMP	Directorate Configuration Management Plan.
DDO	Deputy Director for Operations.
Directorate-level Quality Assurance Plan	A document that defines QA requirements within a directorate or program and also assigns responsibilities and provides guidance for implementation.
Document	Any hard copy or electronic (i.e., text or graphic) information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a record until it satisfies the definition of a record.
Document control	The act of assuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed.
DSA	Documented safety analysis.
ES&H	Environment, safety, and health.
FSP	Facility Safety Plan.

Go forward	The process of establishing configuration management information for CIs where such information is unavailable in support of new modifications or new required analyses. If comprehensive baseline configuration data are not available for CIs, the existing configuration of the CIs shall be maintained. The responsible program may decide to reverse-engineer (reconstitute) the necessary configuration baseline information to ensure the adequate safety basis for the modification to a CI.
Graded approach	A process by which the level of analysis, documentation, and actions necessary to comply with a requirement are made commensurate with various considerations, including relative importance to safety; magnitude of hazards involved; lifecycle stage of the facility; the facility's programmatic mission and particular characteristics; and any other relevant factor (see Section 1.4.1 of DOE-STD-1073-93).
Guidance	A recommended but not mandatory practice.
HAR	Hazard Analysis Report.
ISM	Integrated Safety Management.
OSR	Operational Safety Requirement.
QA	See "Quality assurance."
Quality	Defined in 10 CFR 830.3 as the condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.
Quality assurance (QA)	Actions that provide confidence that quality is achieved.
Quality Assurance Plan	A plan (see Document 41.1) that identifies the Quality Assurance Program implementing requirements applicable to the Laboratory's activities.
Record	A completed document that furnishes evidence of the quality of items or activities affecting quality. In addition to paper (i.e., hard copy), records may include electronic documents and specially processed records such as radiographs, photographs, negatives, and microforms.

Relied upon safety system (RSS)	An SSC (other than safety-class and safety-significant SSCs) relied upon to maintain a facility's safety basis.
RSS	See "Relied upon safety system."
SAD	Safety Assessment Document.
Safety basis	Information derived from an analysis of safety issues relating to the control of hazards that are not commonly accepted by the general public at a facility (controls may be engineered, administrative, or personnel related) that provides reasonable assurance that the facility can be operated safely. Document 3.1, "Safety Analysis Program" and Document 3.2, "Safety Basis Thresholds," in the *ES&H Manual*, discuss the different types of Laboratory safety basis documents for facilities.
Safety envelope	The parameters defining the limits for safe operation of a facility or operation. The range of conditions covered by the safety documentation of a process or facility under which safe operation is adequately controlled. Examples of parameters include the maximum amount of material that may be used or stored, the minimum operating temperature, and the maximum operating pressure.
SAR	Safety Analysis Report.
SC-SSC	Safety-class structures, systems, and components. 10 CFR 830 defines SC-SSCs to include portions of process systems, whose preventive or mitigative function is necessary to limit radioactive hazardous material exposure to the public, as identified by the documented safety analysis (DSA).
SME	Subject-matter expert.
SQR	Safety Question Review.
SSC	Structures, systems, and components.
SSEP	Safety, Security, and Environmental Protection [Directorate].

SS-SSC	Safety-significant structures, systems and components. 10 CFR 830 defines SS-SSCs as those structures, systems, and components not designated as SC-SSCs but whose preventive or mitigative function is a major contributor to defense in depth and/or worker safety as determined from safety analyses.
Status accounting	The process of creating and organizing the knowledge base necessary for the performance of CM. Status accounting provides a reliable source of configuration information to support operational activities.
Technical management review	An assessment of the strengths and weaknesses of existing programs and procedures to determine where upgrades and resources are necessary.
TSR	Technical safety requirement.
USI	Unreviewed Safety Issue.
USQ	Unreviewed Safety Question.
WSS	Work Smart Standard.

Appendix B

Generic Directorate Document Hierarchy Chart